

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

As of May2 , 2012: DailyMed has close to 37,000 SPL loaded.

Notes:

Questions about 2 new items in the latest Implementation Guide, 2.1.9 Core Document Reference, and 2.1.10 Predecessor Document

Predecessor Document: Do we continue to provide the references in subsequent versions. The file is also called the surviving document in informal communications. You include the reference to the SPL you want to replace one time. You should not include the related document element again, since inclusion causes the system to try to look for a previous file.

Core Document Reference: Positron Emission Tomography listings – a lot of these, and a lot of small organizations dealing with the listings for PET drugs. Content of Labeling is the same for the three products every time, and the FDA created a core document reference (Core SPL file) to automatically complete many of the sections.

Review Division is questioning RECONSTITUTED strengths for Lyophilized Products as well as first level of packaging.

- Review Division has asked why we were being questioned about the use of the reconstituted measurements, rather than the non-reconstituted measurements. This was coming from the SPL data elements
- The SPL group has contacted the team leader to provide some refresher information about how the measurements should be displayed.
- SPL group trained the Labeling and Chemists back in 2008, before some of the significant changes that took place. SPL group also meets with Labeling Group once a month to go over any changes in SPL practices, and to provide any new information.
- If you get questions about data elements that seem contrary to what goes on with the validation rules, consider forwarding the Q to spl@fda.hhs.gov

Are others are getting push back from FDA/CMS for incorrect marketing start dates?

- Some background: FDA is encouraging the use of SPL data. CMS is using the data to support reimbursement requests/determination. In 2009, we encouraged the use of the Marketing Start Date to indicate the date when the product would be available (on the market). CMS wants to use the Marketing Start Date at each package level. When the SPL file is released to the public, it should have a marketing start date.
- For new package configurations that may be released in the future, should we wait to submit until the actual marketing start date? Or file now, including the information about the future start date of the new package configuration.
- FDA considers the Marketing Start date to apply at the product-level only.
- Doesn't that mean that the data cannot be extrapolated down to the package/NDC level?
- CMS may release or share information about why & how they use the SPL data.
- NDC-SPL Data Elements file (posted on FDA page) – includes start date for each package. In order to have a start date for each package, the FDA created an algorithm to calculate an approximate market date for each package (using the date of the submission of the version of the SPL first containing the new package as the basis of the calculation). CMS may be using the data for multiple calculations.
- FDA's perspective: there is only one Marketing Start Date. Other dates calculated from the SPL are not used to determine package-level start dates.
- If you cannot identify the true Marketing Start Date, you can use the Actual Approval Date in the Marketing Start Date field. The issue for CMS was often about start dates that were much newer than the actual Marketing Start Date.

What do you do when your approval letter shows the 14 day requirement to submit SPL to eLIST and you are not launching for 6 months?

- At approval, you can market the drug. It is the company's decision when to market. What happens
- Submitting the drug listing with a Future Marketing Start Date does comply with the 14-day requirement, even if the date is in the future. One suggestion – put a date that is very far in the future.
- What if we never market the product, or we create a label specifically for drug listing. How do we file this? You need to include an NDC (perhaps via the use of a code that is only used for the listing)
- Always check with the Review Division if you are thinking of not submitting SPL via Drug Listing for some specific situation.
- Is there a possibility that the FDA could add another date field – specifically for the date to post to DailyMed?

Has anyone been contacted by Lonnie Smith regarding NDA/ANDA Marketing Categories being incorrect?

Original applications were initially approved as NDAs. Recently, the organization was told that these could be treated as ANDAs. There's concern that the change in marketing category may affect the reimbursement (CMS).

CMS had contacted SPL about mismatches in the Orange Book and Drugs@FDA. Many of the mismatches seemed to originate with repackers and relabelers, as they didn't always include NDA or BLA. FDA had been checking against a list in one of the systems that contained the wrong Marketing Category.

Going forward, one suggestion is to match the Orange Book categorizations.

NDA Blood Bags – requiring repeated manual overrides. These require either BN or BA in front of the number.

Is SPL being used on the Drugs@FDA?

Per Lonnie – we use Drugs@FDA for a different purpose. So SPL – at this time – is not posted.

For FDA eSubmitter: any questions about this, contact edrls@fda.hhs.gov

Next meeting scheduled for May 16, 2012.